



Fletcher, J. W. A., Ehrhardt, B., MacLeod, A., Whitehouse, M. R., Gill, H., & Preatoni, E. (2019). Non-locking screw insertion: No benefit seen if tightness exceeds 80% of the maximum torque. *Clinical Biomechanics*, 70, 40-45.

<https://doi.org/10.1016/j.clinbiomech.2019.07.009>

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[10.1016/j.clinbiomech.2019.07.009](https://doi.org/10.1016/j.clinbiomech.2019.07.009)

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### Highlights

No significant further compression generated beyond 80% of the maximum torque

Pullout force unaffected by variations in sub-maximal screw tightness

Stripping limits of screw holes can be reliably predicted prior to insertion

# Non-locking screw insertion: no benefit seen if tightness exceeds 80% of the maximum torque

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James W A Fletcher<sup>a\*</sup>, Beate Ehrhardt<sup>b</sup>, Alisdair MacLeod<sup>c</sup>, Michael R. Whitehouse<sup>d,e</sup>, Harinderjit Gill<sup>c</sup>, Ezio Preatoni<sup>a</sup>

<sup>a</sup> Department for Health, University of Bath, Bath, UK

<sup>b</sup> Institute for Mathematical Innovation, University of Bath, Bath, UK

<sup>c</sup> Department of Mechanical Engineering, University of Bath, Bath, UK

<sup>d</sup> Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School, 1st Floor Learning & Research Building, Southmead Hospital, Bristol, UK

<sup>e</sup> National Institute for Health Research Bristol Biomedical Research Centre, University Hospitals Bristol NHS Foundation Trust and University of Bristol, Bristol, UK

\*Corresponding author:

James WA Fletcher

Applied Biomechanics Suite,

Department for Health,

University of Bath,

Claverton Down,

Bath, BA2 7AY

UK

Email: [jwaf20@bath.ac.uk](mailto:jwaf20@bath.ac.uk)

Declarations of interest: none.

## Word Count

Abstract: 246

Introduction to conclusion: 3458

## 28 Abstract

### 29 Background

30 Millions of non-locking screws are manually tightened during surgery each year, but their  
31 insertion frequently results in overtightening and damage to the surrounding bone. We postulated  
32 that by calculating the torque limit of a screw hole, using bone and screw properties, the risk of  
33 overtightening during screw insertion could be reduced. Additionally, predicted maximum torque  
34 could be used to identify optimum screw torque, as a percentage of the maximum, based on applied  
35 compression and residual pullout strength.

### 36 Methods

37 Longitudinal cross-sections were taken from juvenile bovine tibial diaphyses, a validated  
38 surrogate of human bone, and 3.5 mm cortical non-locking screws were inserted. Fifty-four samples  
39 were used to define the association between stripping torque and cortical thickness. The  
40 relationship derived enabled prediction of insertion torques representing 40 to 100% of the  
41 theoretical stripping torque ( $T_{str}$ ) for a further 170 samples. Screw-bone compression generated  
42 during insertion was measured, followed immediately by axial pullout testing.

### 43 Findings

44 Screw-bone compression increased linearly with applied torque up to 80% of  $T_{str}$  ( $R^2=0.752$ ,  
45  $p<0.001$ ), but beyond this, no significant further compression was generated. After screw insertion,  
46 with all screw threads engaged, more tightening did not create any significant ( $R^2=0.000$ ,  $p=0.498$ )  
47 increase in pullout strength.

### 48 Interpretation

49 Increasing screw tightness beyond 80% of the maximum did not increase screw-bone  
50 compression. Variations in torques below  $T_{str}$ , did not affect pullout forces of inserted screws.

51 Further validation of these findings in human bone and creation of clinical guidelines based on this  
52 research approach should improve surgical outcomes and reduce operative costs.

53 **Keywords:** Insertion torque; fixation failure; tightness; compression; pullout force

54

## 1. Introduction

Non-locking screws are widely used in osteosynthesis to manipulate and stabilise bone fragments. Surprisingly, there is a lack of quantitative assessment in the literature of the best methods for tightening screws in bone. Indeed, once all screw threads are engaged, the benefits of further tightening are unclear in terms of generated axial forces, both compressive and tensile. Non-locking screw insertion for osteosynthesis is predominately performed under subjective control and often imperfectly, with stripping of the surrounding bone occurring with 1 in 4 screws in biomechanical testing (Fletcher et al., 2019). This implies a lack of awareness of the shear limits of bone and/or an inability of surgeons to predict or perceive them. The main consequence of stripping the surrounding bone, occurring when the applied torque exceeds the maximum shear that can be tolerated (stripping torque ( $T_{str}$ )), is a reduction in pullout strength of over 80% (Collinge et al., 2006; Wall et al., 2010). This is a major contributor to fixation failures (Broderick et al., 2013). The sub-maximal tightness that generates the optimum construct, as functions of maximal compressive and pullout forces, is currently unknown. Some studies have found that increasing screw tightness up to  $T_{str}$  generates increased pullout strength (Edwards et al., 2005; Troughton, 2008; Tsuji et al., 2013), yet other studies do not support this conclusion (Cleek et al., 2007; Lawson and Brems, 2001; Ricci et al., 2010). The surgical techniques used to tighten screws have been shown to be highly variable (Feroz Dinah et al., 2011; Gustafson et al., 2016; Stoesz et al., 2014), leading to millions of loose screws being inserted intraoperatively worldwide each year. Whilst screw tightness as a percentage of the maximum possible varies greatly between surgeons, 86% has been suggested to be the average of what is clinically applied (Cordey et al., 1980). However, even if this value is representative of current clinically applied torque, there is no evidence to justify targeting or achieving this figure in terms of creating the optimal construct. Equally, there is no adopted clinical method for predicting this value before screw insertion, hence the flawed technique of subjectively tightening non-locking screws continues.

Comparisons between insertion torque and cortical thickness have been performed, with Gotzen et al. (1976) finding a correlation of ( $r = 0.95$ ) (Gotzen, 1976), and Lawson and Brems (2001) reporting a qualitative correlation (Lawson and Brems, 2001). Cordey et al. (1980) found that cortical thickness did correlate significantly with stripping force for human tibiae ( $r = 0.78$ ), but not significantly for human femora ( $r = 0.48$ ). Equations have been used to predict pullout strength for cylindrical and conical screw designs, finding that with the former design the prediction correlated at  $R^2 = 0.93$  when using an integral formula based on screw geometries and bone mechanical properties (Tsai et al., 2009). Furthermore, similar equations can be used to predict the stripping limit of homogeneous materials (Troughton, 2008; Zdero et al., 2017a). These methods are based on the screw geometry and material properties of the sample receiving the screw, and have been used to confirm stripping values retrospectively in human and artificial bone (Aziz et al., 2014). However, these equations have not been applied predictively to screw fixation in part because of the heterogeneous properties of bone and the intraoperative variability of the depth, direction and shape of screw holes (Messmer et al., 2007). Additionally, they have not been used to address what the optimum torque might be.

This study primarily aimed to assess whether stripping torques can be predicted using cortical thickness and/or an equation based on screw and bone properties, and secondly, to identify if there is a value or range for optimum non-locking screw tightness as functions of screw compression and pullout force.

## 2. Methods

### 2.1 Predicting the stripping torque

Eight tibial diaphyses from four, 4-5 month old juvenile cows, were obtained from a commercial butcher (Bartlett and Sons, Bath, UK) and used within the animal welfare regulations

and guidelines. This bovine bone model has been previously validated as an adequate surrogate of normal density bone, whilst providing reduced variability compared to human models (Fletcher et al., 2018a; Fletcher et al., 2018b). All soft tissues were physically removed, before cutting each bone into 20 mm length cross sections, giving six samples per tibiae. Any residual trabecular bone was removed. Samples were stored in phosphate buffered solution-soaked swabs at -20°C and defrosted for 18 hours before use. Each section had 2.5 mm pilot holes drilled perpendicularly using an automated bench drill with the holes spaced equally around the circumference, at least 18 mm apart (ASTM, 2017). The mean average cortical thickness of each hole was calculated by measuring the cortical thickness once from both sides of the sample with digital Vernier's callipers.

## 2.2 Establishing the relationship between stripping torque and a predictive equation

Self-tapping, fully threaded, non-locking 3.5 mm cortical screws (Stryker, Newbury, UK) were inserted by hand, through a washer into 54 unicortical holes using a torque measuring wrench (DTL-100i Digital Torque Wrench, Checkaline Europe Ltd, Birmingham, UK). Torque moments were recorded until the stripping torque ( $T_{str}$ ) was achieved when the bone stripped around the screw. The relationship between cortical thickness and  $T_{str}$  was evaluated, using linear regression analysis. Next, a predictive equation (Troughton, 2008) was tested for its ability to calculate the stripping torque (Equation 1).

$$T_{str} = \frac{TYS}{\sqrt{3}} \pi \cdot D_p \cdot L \cdot r \cdot \frac{p + 2f \cdot r}{2r - f \cdot p} \text{ (Eq. 1)}$$

Where TYS= tensile yield stress,  $D_p$  = pitch diameter, L = axial length of full thread engagement, r = pitch radius of screw, p = reciprocal of threads per unit length, f = coefficient of friction of the bone-screw interface.



To use this equation, the coefficient of friction between the screw and the bone, and the tensile yield stress of the material need to be calculated. These unknown variables were found using nonlinear, least-squares data fitting in Matlab (v2018b, The MathWorks Inc., Natick, MA, USA). Following this, validation of Equation 1 was performed by using half of the experimental stripping values to recalculate the unknown variables, followed by using Equation 1 to predict the stripping values for the other 27 samples. To find the optimal values, initial conditions for the coefficient of friction and tensile yield stress were set to 0.4 (Parekh et al., 2013; Zdero et al., 2017b), and 90 MPa (Bayraktar and Keaveny, 2004; Cowin, 1989; Parekh et al., 2013; Zdero et al., 2017b), respectively. Regions of search were bound between 0 and 1 for  $f$  and between 1 and 120 MPa for TYS.

### 2.3 Measuring the effect of different percentages of the stripping torque as functions of compression and screw pullout.

To investigate optimum torque, 170 bovine samples were prepared in an identical manner as described above. Custom jigs were used to mount specimens on a materials testing machine (Instron 5967, Instron, High Wycombe, UK) (Figure 1). The same 3.5 mm screws were inserted unicortically by hand through a washer, until at least 2 mm of screw threads protruded from the inner cortex. At least 8 mm of screw threads were left exposed on the near cortex to enable placement onto slotted jigs attached to a 5 kN load cell mounted on the material test machine crosshead (Figure 1). Using cortical thickness of the hole, Equation 1 was used to predict the  $T_{str}$ . Using this value to indicate 100% tightness, six decile target tightness groups were chosen - 40-49%, 50-59%, 60-69%, 70-79%, 80-89% and 90-100% - and the required torque values for each insertion were calculated. This method was performed 170 times with random allocation of each test into a decile group, ensuring at least 25 samples were tested per group. Whilst recording at 20 Hz using data acquisition software (Bluehill 3, Instron, High Wycombe, UK), screws were tightened to the targeted torque using the same digital torque wrench as previously. During insertion, the

compression force and applied torque were recorded simultaneously. Upon reaching the target tightness, the final compression generated was recorded and axial pullout was immediately performed at 5 mm/min (ASTM, 2017; Inceoglu et al., 2004), until the maximum pullout force was achieved and/or free displacement of the screw occurred. To standardise for variations in cortical thickness, forces generated were normalised per mm of cortical thickness (Aziz et al., 2014).

Statistical analysis was performed using a linear regression model to test for an overall effect of cortical thickness (independent variable) on experimental stripping torque (dependent variable), of experimental stripping torque on predicted stripping torque, of screw tightness on pullout force and compression force, and of cortical thickness on raw pullout force. The adjusted  $R^2$  values and the p-values of the F-test were used to indicate how well the model fit the data. For compression forces, we analysed the impact of increasing screw tightness in more detail: we grouped tightness in 10%-blocks and ran a pairwise comparisons between every two of the tightness groups using a two-sided t-test with unequal variances. We adjusted the p-values for multiple testing using Benjamini, Hochberg, and Yekutieli control of the false discovery rate. Results for all statistical analysis were considered significant at an alpha of 0.05. All statistical tests were performed with 'R' software, v3.3.3 (R: A language and environment for statistical computing. R Foundation for Statistical Computing). Data is available via an online data repository [[\*DOI to be created\*](#)].

### 3. Results

Cortical thickness demonstrated a linear relationship with experimental stripping torque;  $R^2 = 0.869$ ,  $P < 0.001$  (Figure 2). Non-linear optimisation generated a coefficient of friction for the bone-screw interface of 0.336 and a tensile yield stress of 75.67 MPa. Comparing the predicted stripping torque, using Equation 1, to the experimental stripping torque generated an  $R^2 = 0.881$ ,  $P < 0.001$  (Figure 3). The non-linear optimisation based on half of the initial samples ( $n=27$ ) found a coefficient

of friction of 0.337 and a tensile yield stress of 75.87 MPa, with compared to Equation 1 predictive stripping torque showing a relationship of  $R^2=0.830$ ,  $P<0.001$ .

Seven samples were detected to have been inadvertently stripped during insertion, where peak torque occurred before the targeted experimental torque was achieved; these data were excluded from analysis. Statistical analysis was performed for the remaining 163 samples. Using the continuous measurements of compression as more torque was applied ( $n=509$ ), as screw tightness increased from seating torque (where the screw head first exerts compression) to 80% of the maximum torque, compression increased in a linear fashion ( $R^2 = 0.752$ ,  $P<0.001$ ). Grouping the samples based on their final tightness decile groups, further increases in tightness from 70 to 79%, to 80 to 89% and to 90 to 100% did not generate any significant increase in compression ( $P=0.22$  and  $0.14$  respectively) (Figure 4). No significant difference in the normalised pullout force was found as tightness increased between 40 and 100% of  $T_{str}$  ( $R^2 = 0.000$ ,  $P=0.498$ ) (Figure 5). Cortical thickness was found to be predictive of raw pullout force ( $R^2 = 0.484$ ,  $P<0.001$ ).

#### 4. Discussion

Identifying the stripping limits of bone samples, using predictions based on cortical thickness, enables calculation of the specific tightness targets. Using the methods described establishes a foundation for developing techniques to improve screw insertion, making screw use more effective. Additionally, discovering a value that beyond which no construct benefits as functions of compression and pullout forces are generated – which was found between 70 and 80% of the stripping torque – provides surgeons with an evidence-based tightness to target.

Increasing tightness generates greater friction between the screw and the interthread bone. As the screw head prevents further penetration of the screw through the cortical bone, more rotation exhibits a tensile force on the bone, based on the resultant force and the coefficient of

friction at the bone-screw interface. It has previously been shown experimentally that the compression force generated during tightening is directly proportional to the amount of torque applied (Perren et al., 2000; Ricci et al., 2010). This is seen within this study with the initially linear relationship between compression and increasing tightness; however, beyond 80% of the maximum torque, no further benefits were seen, which we speculate to be explained by increasing frictional forces becoming balanced by increasing plastic deformation occurring around the screw threads. Extra motion from a less stable construct may have benefits as more motion at the fracture site may stimulate greater bone healing. However, reduced screw purchase may generate micromotion at the bone/screw interface, leading to the creation of fibrous tissue rather than neobone formation (Kenwright et al., 1986; Wallace et al., 1994). Further to this, the damage caused in stripping bone around screw threads may impact on the healing potential of the fracture site (Cleek et al., 2007).

Pullout force did not vary as a function of tightness. We postulate that during screw insertion, a tensile force is applied to the material between the threads. This causes failure independent of the failure mechanism seen during screw pullout, so long as the maximum stripping torque has not been reached during insertion. If stripping occurs, this disconnects the bone between the screw threads and that surrounding the screw, considerably reducing the overall construct's ability to resist axial force. However, if the maximum insertion torque is not exceeded during insertion, the interaction between the screw threads and the bone does not affect the force that can be applied to the construct as a whole; the pullout force of a screw is determined by the deformation at the boundary of the outer threads and the bone, not by changes in the bone within the threads. This is seen with the failure mechanism that occurs during pullout being shearing of the material at the edge of the outer diameter of the screw, evidenced with the 'corkscrew' of material that often remains within the screw threads following pullout testing; also observed by others (Cleek et al., 2007). Given that variations in screw tightness only effect compression (torques below  $T_{str}$  being found to not affect pullout force), optimum tightness as functions of compression and pullout force can be defined purely on its effect on the former - approximately 70 to 80% of the  $T_{str}$ .

Although in vitro pullout strength may not change with tightness when tested immediately, there may be ramifications in vivo from excessive torque in terms of compromised bone remodelling from any damage caused from overtightening. Furthermore, as there do not appear to be benefits of tightening screws closer to the manually undetectable, irreversible stripping torque, tightening screws to the levels seen in some biomechanical papers seems unwise (Fletcher et al., 2019).

A frequently quoted, although historic, paper by Cordey et al. (1980) reports that surgeons tighten screws to 84% (SD 13) of the maximum torque in cadaveric tibiae and 88% (SD 18) in cadaveric femora; averaged to 86% (Cordey et al., 1980). However, generalising this paper to describe what is clinically achieved is flawed, as the value was generated by asking surgeons (both orthopaedic and general surgeons) to tighten only one 4.5 mm screw into cadaveric tibiae (n=63) and femora (n=35); using this figure to describe other situations should be performed cautiously, if at all. Collating data from the literature on achieved screw tightness has shown values of 78% (SD 10) for cortical (n=1079) and 80% (SD 6) for cancellous screw insertions (n=431) (Fletcher et al., 2019). However, what surgeons subjectively achieve and what is optimal for constructs may well be different, as shown by our data. One of the key improvements in this research compared to previous studies is the control of the insertion torque including not using subjective measurements such as surgeon's predictions. Subjective feel related to applied torque is highly variable (Fletcher et al., 2019), however insertion torques are almost always not mentioned in biomechanical studies. This study highlights that when testing screw/bone interactions, especially when variations in compression may alter outcomes, the tightness of screws needs to be measured. In part, to ensure that screws have not stripped the material on insertion, but also as the occurrence of stripping is poorly detected by surgeons (Stoesz et al., 2014).

Previous studies comparing compression and applied torque have reported a directly proportional relationship (Cordey et al., 1980; Egol et al., 2004; Perren et al., 2000; Ricci et al., 2010), which appears to only be correct up to 80% of the stripping torque. However, no studies have

quantitatively assessed optimum tightness as functions of compression and pullout force. Cleek et al. (2007) measured pullout force for screws inserted to 50%, 70% and 90% of the maximum (the maximum being determined by the stripping torque of a contralateral ovine tibiae hole), with the preload (compression) being removed before pullout testing (Cleek et al., 2007). In their study, where 3.5 mm screws were inserted into 2.7 mm pilot holes using a washer, they described qualitatively that the compression generated linearly correlated with the applied torque in the initial tightening, before non-linearly increasing. Regarding pullout force, they reported that there was no difference for screws tightened between 50% and 90% of the maximum tightness, nor between 50% and 70%, but that there was a difference between 70% and 90% ( $P < 0.05$ ). Whilst they followed the manufacturer's recommendation, common practice involves inserting 3.5 mm screws into 2.5 mm pilot holes (unless using cannulated screws, which these were not stated as being), thus their pilot holes are likely to have affected their results (Battula et al., 2008). Of their tests to determine the failure torque, 33% had to be discarded for methodological reasons resulting in only 20 samples being available for analysis and, whilst the targeted percentages cover a spectrum of those seen, only three discrete values were tested.

Lawson and Brems (Lawson and Brems, 2001) compared screws inserted to 10%, 50%, 90% of the maximum torque and one group of screws inserted to >100% of the maximum. Using juvenile ovine femora, they found a difference between the stripped samples and the others, but no significant difference in the maximum pullout force between any non-stripped groups. In further tests, they stated that unicortical and lag screws should not be inserted beyond 65% of the maximum, though tests were only performed at ~10% and ~68% of the maximum torque, and with stripped samples. Cleek et al. (2007) reported that they did not find a reduction in the pullout force of that found by Lawson and Brems because they released the compression generated prior to axial pullout testing. However, this explanation is unclear, as we found that so long as the compression force is less than the pullout force generated, it can be ignored when interpreting the pullout; as

failure occurs by shearing the bone at the extremities of the screw threads, rather than between them.

There are limitations with the methods utilised in this study. The relationship between tightness and force is based on theoretical calculations of the insertion torque as a percentage of the stripping torque. Firstly, it is based on perfect insertion of all screw threads into an isotropic homogeneous material, and secondly, given variations in both the samples and the accuracy of measuring cortical thickness, a targeted percentage may be different to the actual torque required for that percentage. Indeed, seven samples (4%) were stripped on insertion when a predicted torque value below 100% transpired to be experimentally above it.

Using an in-vitro bovine model reduces specimen variability, especially compared to using human bone (Fletcher et al., 2018b), whilst demonstrating similar properties to human bone (Cowin, 1989; Evans, 1976; Hobatho et al., 1992; Swartz et al., 1991)). Furthermore, it offers lower variability and less ethical and financial restrictions to other testing models and an increase in power for the same effect size compared to alternative methods used in papers with similar aims (Aziz et al., 2014; Cleek et al., 2007; Lawson and Brems, 2001). However, the findings may not represent the behaviours occurring with in-vivo human bone. In vivo insertion torques have been found to be higher than in vitro torques, for example with spinal pedicle screws (Buhler et al., 1998), though we postulate that the trends found should still be the same, even if the raw values are not.

Unicortical insertion was performed to reduce the number of animal specimens needed, and because bicortical insertion would have considerably reduced the chance of both cortices being engaged perpendicularly, given the shape of the tibial diaphyses. Lawson and Brems (2001) found that for axial pullout, it is the total cortical thickness that linearly correlates with the stripping torque, rather than whether the cortical thickness is generated from one or two cortices (Lawson and Brems, 2001). However, the findings from unicortical situations within this study may not be generalisable to bicortical fixation. Washers were used to model plates pressing against the

periosteum, which may explain some of the differences in the results between this study and others assessing maximum pullout force; pullout capacity may be overestimated if there is a higher concentration of load more distally due to a lack of proximal restraint (MacLeod et al., 2015).

Whilst a very common testing method, axial pullout testing is not necessarily an appropriate model of in vivo screw failure, which is typically through progressive loosening rather than a single episode of catastrophic failure. However, this testing method is recognised as a standardisable way of controlling variables (ASTM, 2017), and ensures that trends can be seen, and comparisons made, even if the raw values are not fully representative. Furthermore, the failure rate was rapid, and did not allow for stress relaxation to occur following screw insertion. Though this may have elevated the raw values of the forces seen, the trends should remain the same (Inceoglu et al., 2004).

## 5. Conclusion

Non-locking screws should be tightened to between 70% and 80% of the maximum torque. As pullout force does not change with screw tightness once all threads are engaged, insertion should be optimised for compression. More tightness, once the screw head is seated, was not found to generate more pullout force. Establishing optimum tightness for screws in fracture fixation will reduce failure rates especially given the current incidence of overtightened screws. Further work is needed to corroborate these findings in human bone, alongside development of methods for predicting stripping limits in bone pre and/or intraoperatively.

## Acknowledgements

We thank Nick Waywell and Jack Howell from the University of Bath for help with apparatus construction and David Whitfield from Stryker for supplying the screws. This work was supported by a grant from the Royal College of Surgeons of England.



## Conflict of interest and sources of funding

This study was performed with the assistance of the Royal College of Surgeons of England, Surgical Research Fellowship (JWAF). This study was supported by the NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol (MRW). The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care. For the remaining authors none were declared. The funding sources had no involvement in the study design, the analysis and interpretation of data, in the writing of the report nor in the decision to submit the article for publication.

## Figure Legend

Figure 1 – Testing apparatus to continuously record compression whilst applying increasing tightness using a torque wrench, followed by immediate axial pullout.

Figure 2 – The relationship between experimental stripping torque and cortical thickness for 54 juvenile bovine samples.

Figure 3 - The relationship between predicted stripping torque calculated using Equation 1 and the experimental stripping torque for 27 samples.

Figure 4 – Box and whisker plot of normalised compression force (N/mm) in decile groupings as functions of screw tightness (as a percentage of the stripping torque) (n=163). Boxes indicate interquartile range, with a median line. Whiskers indicate maximum and minimum range. # indicates the non-statistically significant comparisons;  $P > 0.05$ .

Figure 5 – Box and whisker plot of normalised pullout force (N/mm) in decile groupings as functions of screw tightness (as a percentage of the stripping torque) (n=163). Boxes indicate interquartile range, with median line. Whiskers indicate maximum and minimum range. All comparisons between decile groups were not significant;  $P > 0.05$ .

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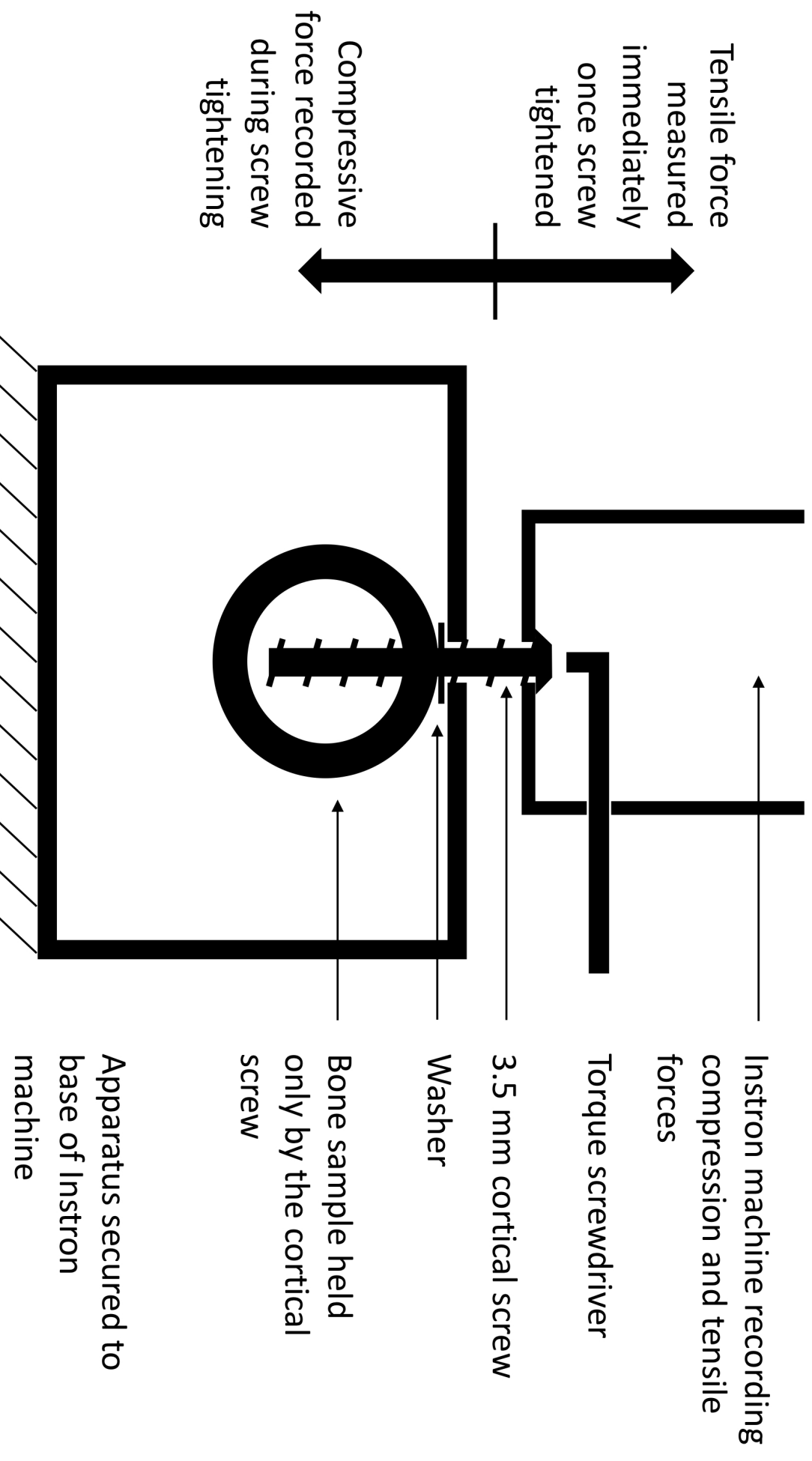
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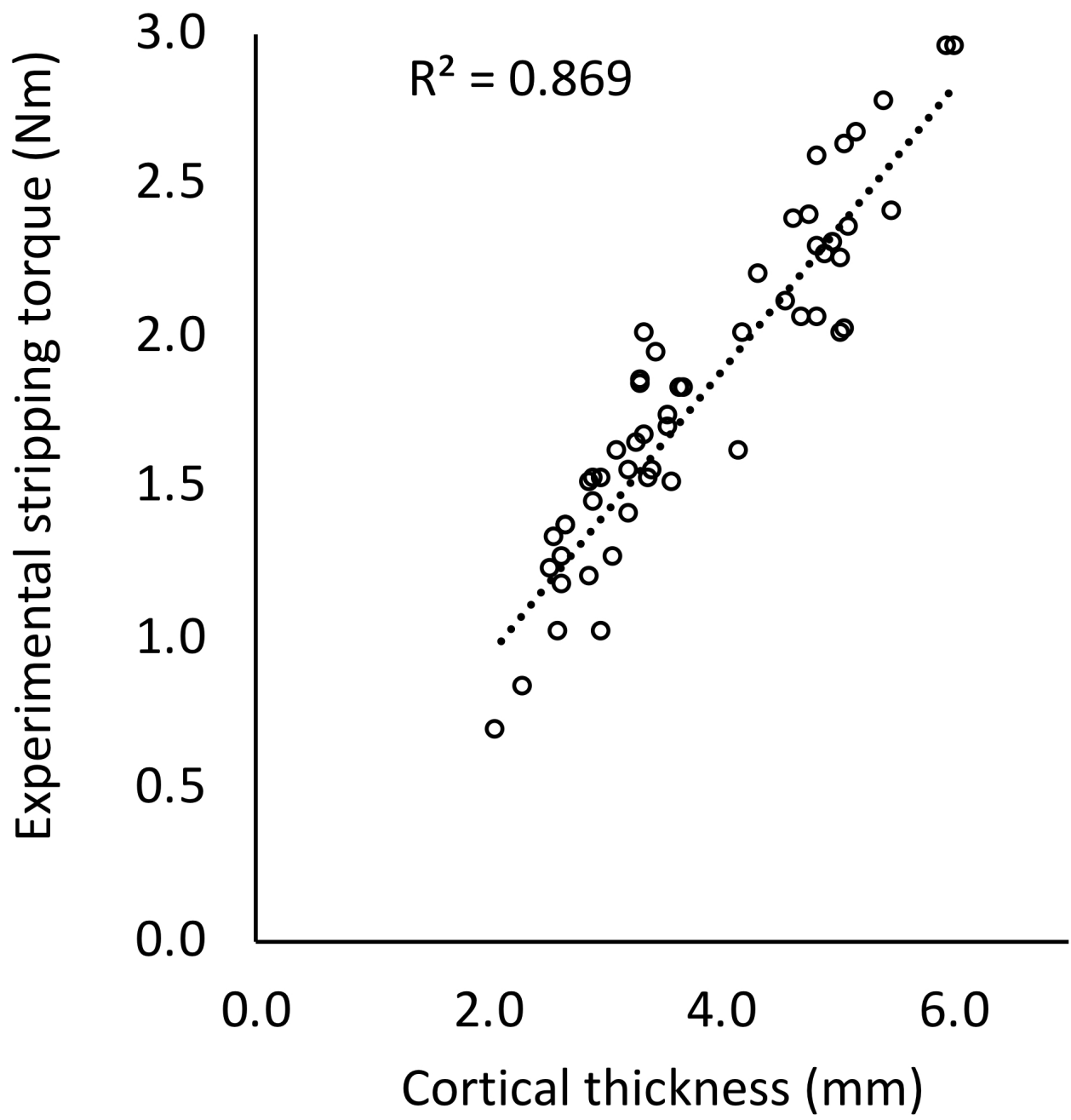
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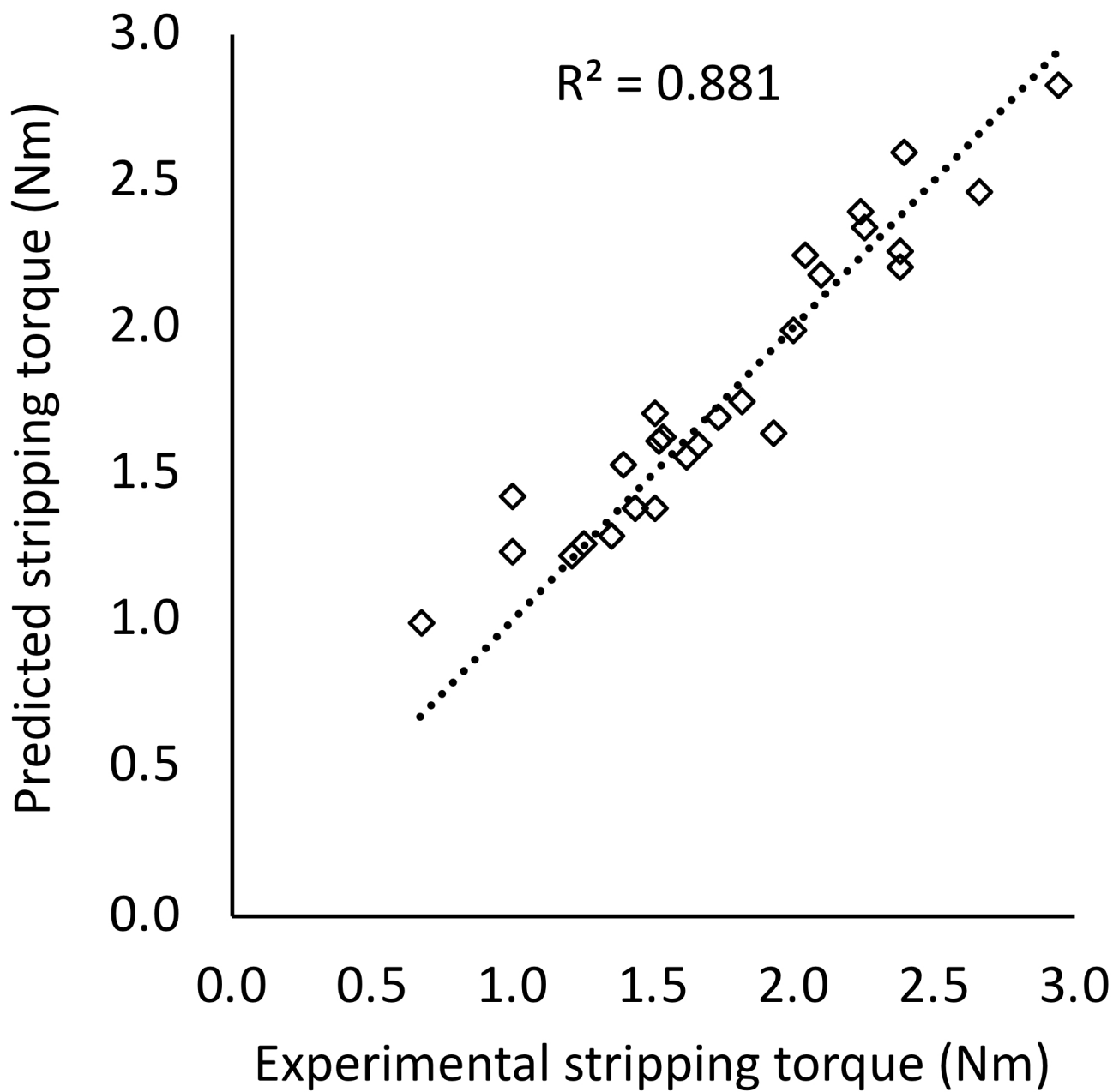
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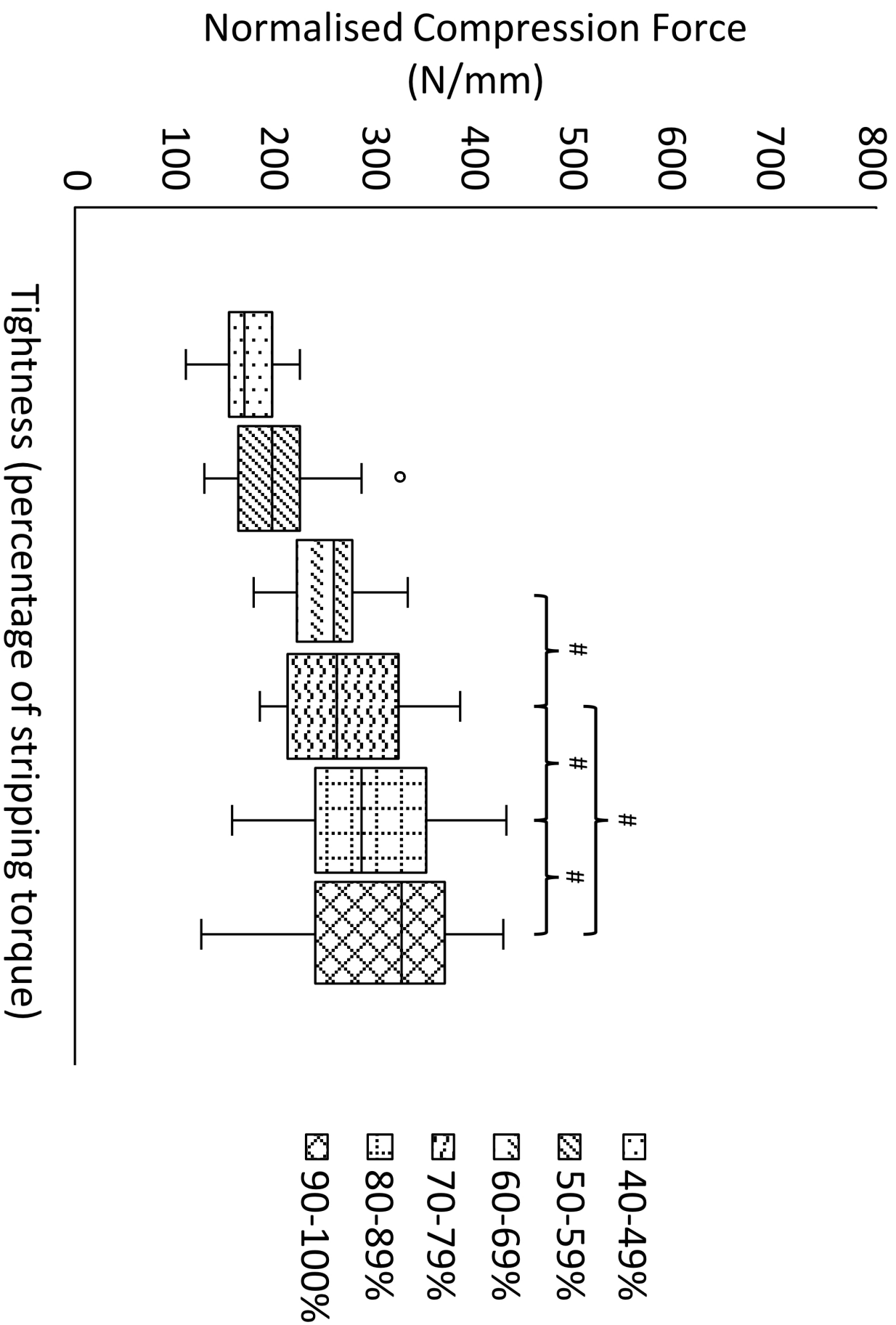
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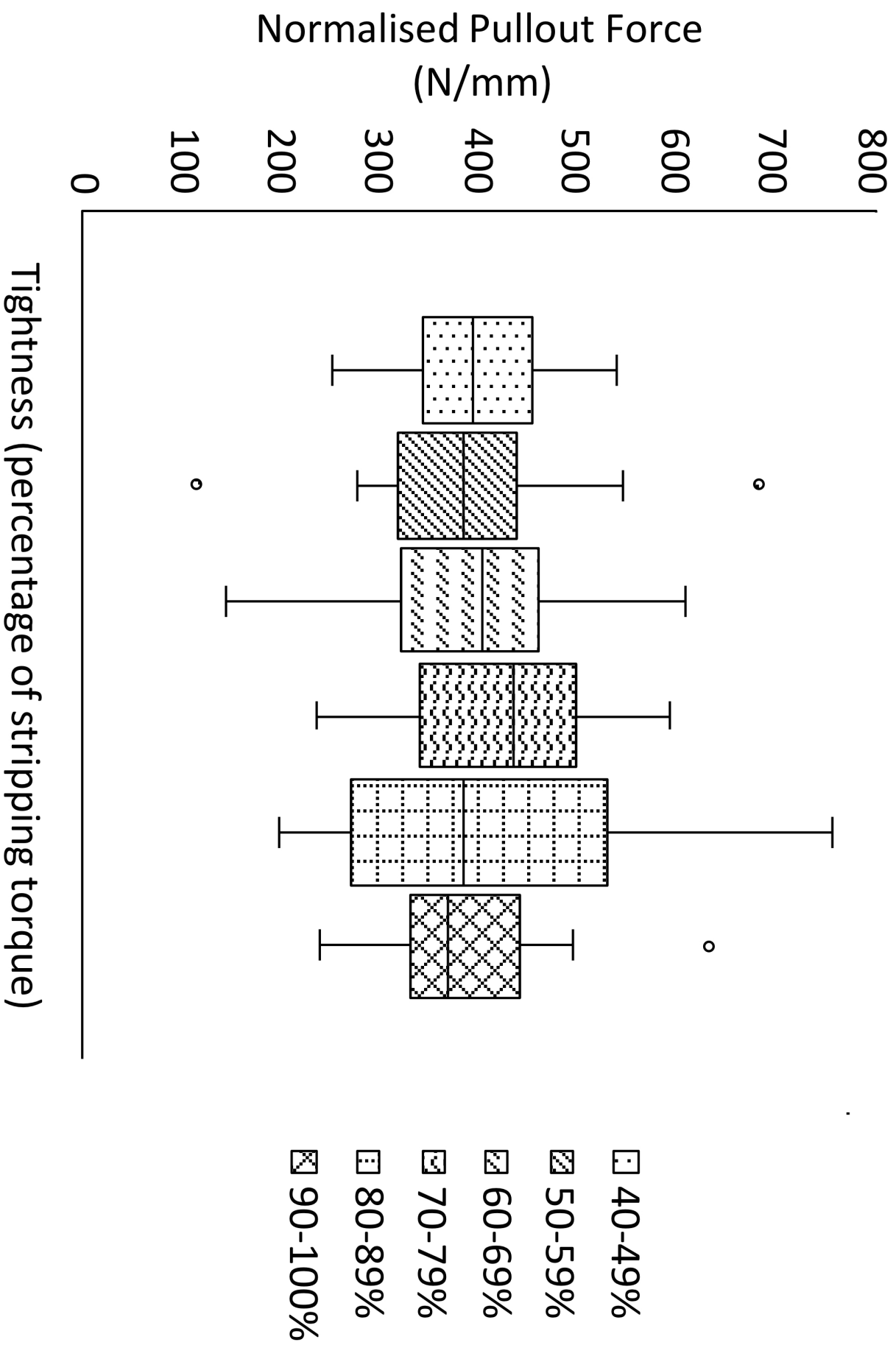












## **Conflict of interest and sources of funding**

Declarations of interest: none.

This study was performed with the assistance of the Royal College of Surgeons of England, Surgical Research Fellowship (JWAF). This study was supported by the NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol (MRW). The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care. For the remaining authors none were declared. The funding sources had no involvement in the study design, the analysis and interpretation of data, in the writing of the report nor in the decision to submit the article for publication.

## **CRediT author statement**

**James Fletcher:** Conceptualization, Methodology, Validation, Formal Analysis, Investigation, Resources, Data Curation, Writing- Original draft preparation, Visualization, Project Administration, Funding Acquisition. **Beate Ehrhardt:** Data curation, Writing- Original draft preparation, Writing- Reviewing and Editing **Alisdair MacLeod:** Methodology, Investigation, Writing- Reviewing and Editing. **Michael Whitehouse:** Methodology, Writing- Reviewing and Editing, Supervision. **Harinderjit Gill:** Software, Validation, Methodology, Resources, Supervision **Ezio Preatoni:** Software, Validation, Resources, Writing- Reviewing and Editing, Supervision.